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REMARKS

Claims 1, 3, 6-8, 26-28, and 32-38, of which 1 and 32 are independent in form, are presented for examination. Claim 1 recites a stent including an alloy comprising tungsten and rhenium, wherein tungsten is present in an amount ranging from about 75 weight percent to about 99 weight percent. Claim 32 recites a stent including an alloy comprising tungsten and rhenium, wherein rhenium is present in an amount ranging from about 1 weight percent to about 25 weight percent.

The Examiner has rejected the claims under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,443,498 ("Fontaine") in view of U.S. Patent No. 5,628,787 ("Mayer"), further in view of U.S. Patent No. 5,226,909 ("Evans"), and further in view of "Rhenium and Molybdenum/Tungsten Based Alloys: An Overview of Database" ("Bryskin"). But this rejection is improper because none of the cited references would have suggested to those of ordinary skill in the art that they should make the claimed stent and that there would have been a reasonable expectation of success.

Before discussing the impropriety of the rejection, Applicants would like to remind the Examiner of the framework for a 35 U.S.C. § 103(a) analysis. In *In re Vaeck*, 947 F.2d 488, 493 (1991), the Federal Circuit explained that:

A proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed [device]; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill in the art would have a reasonable expectation of success.

The Federal Circuit also has explained that a "reasonable expectation of success" cannot be based on hindsight knowledge that an inventor subsequently successfully makes the device. For example, in *Life Technologies, Inc. v. Clontech Laboratories, Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000), the Court explained:

That the inventors were ultimately successful is irrelevant to whether a person of ordinary skill in the art, at the time the invention was made, would have reasonably expected success.... The Court's finding to the contrary represents

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impermissible use of hindsight – using the inventors success as evidence that the success would have been expected.

Here, the Examiner has relied on Fontaine for disclosing a stent formed of a radiopaque material, such as tantalum. The Examiner has acknowledged that Fontaine does not disclose or suggest a stent formed of an alloy comprising tungsten and rhenium alloy as claimed, and has relied on the secondary and tertiary references for the missing claim features.

But none of the cited references discloses or suggests a stent formed of an alloy comprising tungsten and rhenium alloy, as claimed.

Mayer discloses a clad composite stent including, for example, a radiopaque core surrounded by a case. Mayer indicates that the radiopaque core can include *metals* (i.e., not alloys) such as gold, tungsten, iridium, rhenium, ruthenium, and depleted uranium (*see, e.g.,* Mayer, col. 7, lines 7-9), or alloys such platinum-iridium and platinum-nickel (*see, e.g.,* Mayer, col. 10, lines 60-64; and col. 11, lines 9-11). Mayer does not teach “that tungsten-rhenium alloy is highly radiopaque and suitable for medical devices”, as asserted (but unsupported) by the Examiner. As indicated above, Mayer does not disclose or suggest a radiopaque alloy that includes tungsten and rhenium at all, let alone a stent having an alloy that includes tungsten and rhenium, as claimed. Thus, Mayer does not suggest to those of ordinary skill in the art that they should make a stent including an alloy having tungsten and rhenium; and Mayer does not reveal that in so making a stent including an alloy having tungsten and rhenium, those of ordinary skill in the art would have a reasonable expectation of success. *See In re Vaeck*. As a result, it is not clear how Mayer can address the deficiencies of Fontaine indicated above.

Evans has nothing to do with stents. Rather, Evans is directed to an atherectomy catheter 10 having a cutting blade 18 disposed with the interior of a cylindrical housing 14. Evans discloses that the blade and/or the housing can be made radiopaque, and what materials are suitable for use:

For all of the embodiments discussed above, it will be possible to coat or fill the housings and/or cutting blades with a radiopaque material or filler in order to facilitate viewing under a fluoroscope. *Suitable* radiopaque coating materials include palladium and gold, with bismuth, barium, and tantalum being suitable as fillers.

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(Evans, col. 7, lines 36-42, emphasis added.)

But when it comes to a tungsten-rhenium alloy, Evans does *not* indicate that the alloy is suitable for use. Instead, Evans uses the phrase "*may* be constructed" before mentioning a tungsten-rhenium alloy:

Alternately, they [the housing and/or cutting blades] *may* be constructed of radiopaque materials such as tungsten-rhenium or nitinol.

(*Id.*, col. 7, lines 42-43, emphasis added.) Such language is at most an invitation to conduct further research to determine whether a tungsten-rhenium alloy would be suitable in a blade and/or a housing of an atherectomy catheter, not a stent. There is no indication whatsoever to those of ordinary skill in the art that they should make a stent to include an alloy having tungsten and rhenium, as claimed.

Furthermore, Evans does not provide a reasonable expectation that any alloy including tungsten and rhenium, let alone the specific alloys required by the claims, actually could be used successfully in a stent. Evans, at best, is inviting further research to be conducted to determine whether a tungsten-rhenium alloy would be suitable in a blade and/or a housing of an atherectomy catheter as a coating or as a filler. A stent, on the other hand, is a medical device typically used to support the wall of a body lumen and maintain patency. The stent is usually delivered in a small diameter condition through a tortuous body lumen to a treatment site and then expanded into contact with vessel wall where it remains for extended periods. Given this challenging application, an important factor in the performance of the stent is the material from which it is made. In particular, the choice of material includes consideration of a combination of mechanical properties, such as tensile strength and ductility, radiopacity, and metallurgical properties, such as resistance to stress cracking and corrosion. There is no teaching or suggestion whatsoever in Evans that any alloy including tungsten and rhenium could be used in a stent with a reasonable expectation of success.

Thus, Evans does not meet either of the *Vaeck* criteria.

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Moreover, insofar as the Examiner is asserting that because a tungsten-rhenium alloy is used in one specific medical device (the atherectomy catheter), then it would have been obvious to use the alloy in any other medical device (namely, a stent), the Examiner is applying an improper obvious-to-try standard. *See Jones v. Hardy*, 727 F.2d 1524, 1530 (Fed. Cir. 1984) ("Obvious to try" is an improper consideration in a 35 U.S.C. § 103 analysis.) As discussed above, there is no teaching or suggestion whatsoever that an alloy including tungsten and rhenium could be used in a stent with a reasonable expectation of success.

The Examiner has indicated that it would be obvious to one of ordinary skill in the art to use a tungsten-rhenium alloy of the compositions taught by Bryskin in the stent of Fontaine, and the Examiner has pointed to the website for Rhenium Alloys, Inc. (www.rhenium.com/Materials/WRe/tungsten.html) ("Rhenium Alloys"), for its alleged suggestion that tungsten-rhenium alloys are excellent for medical applications. Neither of these references meet either of the *Vaech* criteria.

Bryskin teaches nothing about stents. At best, Bryskin vaguely discloses that tungsten-rhenium compositions are known to have suitable mechanical properties for forming medical devices, but Bryskin does not indicate what the medical devices are. Rather, Bryskin states that tungsten-3 to 5 rhenium and up to 10 rhenium compositions have been found to be very attractive for fabrication of products such as x-ray targets and heat sinks (*see, e.g.*, page 14, lines 15-17). These alloys can be used in x-ray targets apparently because of their ability to dissipate heat and low vapor pressure, as the x-ray target (specifically, the focal point of the anode in an x-ray tube) can get very hot where an electron beam strikes the target.¹ But the fact that these alloys have good heat dissipation capabilities when used, for example, in x-ray targets, does not teach anything about their suitability for use in medical devices generally or in stents specifically. Thus, like Evans discussed above, there is no indication whatsoever in Bryskin to those of ordinary skill in the art that they should make a stent to include an alloy having tungsten and rhenium, as claimed. There is no teaching or suggestion whatsoever in Bryskin that its alloys including tungsten and rhenium could be used in a stent with a reasonable expectation of success. In other words, like Evans, Bryskin does not meet either of the *Vaech* criteria.

¹ *See, e.g.*, compepid.tuskegee.edu/syllabi/clinical/small/radiology/chapter3.html

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Applicants had previously argued that Bryskin does not provide sufficient evidence that its alloys are suitable for medical devices. In response to Applicants' arguments, the Examiner stated,

Bryskin is not relied upon for this teaching. Bryskin is relied upon for providing examples of common W-Re compositions and mechanical properties of these compositions. In the abstract, Bryskin states that the W-Re alloys disclosed in the paper are common (line 8). In lines 14 and 15 on page 3, Bryskin states that the W-Re alloys are very attractive for x-ray targets.

(see page 4 of the Office Action, emphasis added). The Examiner's response, however, is contrary with the Examiner's apparent motivation to combine Bryskin with Fontaine:

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use a tungsten-rhenium alloy of the compositions taught by Bryskin in the modified Fontaine stent, as ***Bryskin teaches that these common W-Re compositions are known to have suitable mechanical properties for forming medical devices.***

(see page 3 of the Office Action, emphasis added.) Bryskin does not indicate what the medical devices are, so the Examiner's characterization of Bryskin's alloys as having suitable mechanical properties for forming any medical devices lacks support and is overly broad. At best, Bryskin indicates that the alloys can be used in x-ray targets, but this indication does not teach anything about the suitability of the alloys for use in medical devices generally or in stents specifically. Also, Applicants do not dispute the alloys may have been known, but the issue is whether there is any indication or suggestion in the reference that would have suggested to those of ordinary skill in the art that they should make a stent with the alloys, or that the alloys could be used in a stent with a reasonable expectation of success. Here, Bryskin does not provide any such indication or suggestion, and the Examiner has not provided any reasoning of how alloys having properties suitable for an x-ray target would have motivated one skilled in the art to use the same alloys in a stent.

Rhenium Alloys also teaches nothing about stents. At best, Rhenium Alloys discloses that tungsten-rhenium alloys are excellent for medical applications, but Rhenium Alloys provides no examples of a "medical application". Instead, Rhenium Alloys focuses on the thermal

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properties of tungsten-rhenium alloys with statements such as "its greatest quality is arguably its ductility after exposure to heat", "tungsten-rhenium (W-Re) maintains a much greater ductility due to its rhenium content" and "if it's hot, you need tungsten-rhenium". But the fact that these alloys have good ductility after exposure to heat or can be exposed to extreme heat does not teach anything about their suitability for use in medical *devices* generally or in stents specifically. As used by Rhenium Alloys, a medical *application*, when read in context, could range anywhere from x-ray targets (for general medical diagnostic and angio- and cardiography to computer tomography) to isotopes for cancer radio-treatment.² Thus, like the other cited references discussed above, there is no indication in Rhenium Alloys to those of ordinary skill in the art that they should make a stent to include an alloy having tungsten and rhenium, as claimed. There is no teaching or suggestion in Rhenium Alloys that its alloys including tungsten and rhenium could be used in a stent with a reasonable expectation of success. Like the other cited references, Rhenium Alloys does not meet either of the *Vaech* criteria.

In response to Applicants' previous arguments, the Examiner stated,

On the website for Rhenium Alloys, Inc. (provided in the Office Action dated 6/23/04), it is specifically stated in line 6 that tungsten-rhenium alloys are excellent for medical applications. There is sufficient motivation and evidence in the prior art to form a stent as set forth in the claims.

(see page 4 of the Office Action.) Again, Rhenium indicates that the alloys can be used in "medical applications", but this indication does not teach anything about the suitability of the alloys for use in medical devices generally or in stents specifically. Also, Applicants do not dispute the alloys may have been known, but the issue is whether there is any indication or suggestion in the reference that would have suggested to those of ordinary skill in the art that they should make a stent with the alloys, or that the alloys could be used in a stent with a reasonable expectation of success. Here, Rhenium Alloys does not provide any such indication or suggestion. The Examiner has simply made a conclusory statement, and has not provided any reasoned analysis of how alloys having properties suitable for an x-ray target would have motivated one skilled in the art to use the same alloys in a medical device, let alone a stent.

² See, e.g., www.plansee.com/hlw/537_ENG_HTML.htm; and www.ne.doe.gov/home/9-21-98.html

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Applicants have provided a detailed analysis of why the 35 U.S.C. § 103(a) rejection is improper. The Examiner has acknowledged that Fontaine does not disclose or suggest a stent including the claimed alloy. As discussed above, none of the other cited references would have suggested to those of ordinary skill in the art that they should make a stent with the claimed alloys, or that an alloy including tungsten and rhenium could be used in a stent with a reasonable expectation of success.

The rejection, on the other hand, is cobbled together with the reasoning that because one radiopaque material (namely, tantalum) has been used in a stent, then any other radiopaque material (such as tungsten-rhenium) used in any other medical device could be applied to a stent. This is clearly an improper rejection based on an obvious-to-try standard. Indeed, none of the cited references teaches or suggests that an alloy including tungsten and rhenium used in a stent would have a reasonable expectation of success. And the Examiner has not made any assertion with regard to a reasonable expectation of success.

For at least the reasons discussed above, Applicants request that the 35 U.S.C. § 103(a) rejection be reconsidered and withdrawn. Applicants believe that the claims are in condition for allowance, which action is requested.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

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